AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-19. Cancelled

20. (Currently amended) A process for manufacturing a two-layer breast prosthesis comprising the steps of:

a) providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening ~~extending from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes~~;

b) at least partially filling the second interior volume of step a) by passing a curable elastic material precursor through the second fill opening;

c) at least partially filling the first interior volume of step a) by passing a self-shaping dispersion through the first fill opening;

d) sealing the first and second fill openings; and

e) curing the elastic material precursor in the second film envelope to provide a two-layer breast prosthesis comprising a cured elastic material layer and an uncured self-shaping layer.

21. (Currently amended) The process of Claim 20, wherein step e) ~~further comprising~~ comprises heat treating the joined first film envelop and second film envelope in a mold having a surface design configured to a desired shape of a breast to thereby cure the elastic material precursor in the second film envelope and to provide a two-layer breast prosthesis having the desired breast shape.

22. (Previously amended) The process of claim 20, wherein step d) further comprises sealing the first and second fill openings simultaneously.

23. (Original) The process of claim 20, wherein step a) further comprises sealably affixing an interstitial plastic film extending between and to a first and a second exterior plastic film, respectively, along their respective common edges to thereby form the first film envelope and the second film envelope joined to the first film envelope.

24. (Original) The process of claim 23, wherein the interstitial plastic film and the first and second exterior films are each comprised of polyurethane.

25. (Currently amended) The process of claim 20, wherein the curable elastic material precursor of step b) comprises a silicone gel and a plurality of microspheres.

26. (Original) The process of claim 20, wherein the self-shaping dispersion of step c) comprises a silicone oil and a plurality of microspheres.

27. (New) The process of Claim 26, wherein the self-shaping dispersion further comprises a thixotropic additive.

28. (New) The process of Claim 26, wherein the microspheres have an average particle size in the range of from approximately 40 microns to approximately 125 microns.

29. (New) The process of Claim 26, wherein the silicone oil has a viscosity in the range of from approximately 100 CSt to approximately 5000 CSt.

30. (New) The process of Claim 29, wherein the silicone oil has a viscosity of approximately 500 CSt.

31. (New) The process of claim 20, wherein the first and second fill openings extend from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes.

32. (New) The process of Claim 20, wherein prior to step c) dissolved air is removed from the self-shaping dispersion.

33. (New) The process of Claim 32, wherein step c) comprises pumping the self shaping dispersion through the second fill opening and into the second interior volume in a closed configuration that does not allow the self shaping dispersion to become aerated.

34. (New) A process for manufacturing a two-layer breast prosthesis comprising the steps of:

a) providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening;

b) at least partially filling the second interior volume of step a) by passing a curable elastic material precursor through the second fill opening;

c) at least partially filling the first interior volume of step a) by passing a non-crosslinking self-shaping dispersion through the first fill opening, wherein the dispersion comprises a plurality of microspheres dispersed in a silicone oil;

d) curing the elastic material precursor in the second film envelope to provide a two-layer breast prosthesis comprising a cured elastic material layer and an uncured self-shaping layer.

35. (New) The process of claim 34, wherein the curable elastic material precursor of step b) comprises a silicone gel and a plurality of microspheres.

36. (New) The process of claim 34, wherein the first and second fill openings extend from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes.

37. (New) The process of Claim 34, wherein prior to step c) dissolved air is removed from the self-shaping dispersion.

38. (New) The process of Claim 37, wherein step c) comprises pumping the self shaping dispersion through the second fill opening and into the second interior volume in a closed configuration.

39. (New) A process for manufacturing a two-layer breast prosthesis comprising the steps of:

a) providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening;

b) at least partially filling the second interior volume by passing a curable elastic material precursor through the second fill opening;

c) at least partially filling the first interior volume with a vacuum treated non-crosslinking self-shaping dispersion by pumping the vacuum treated non-crosslinking self shaping dispersion through the first fill opening in a closed configuration; and

d) curing the elastic material precursor in the second film envelope to provide a two-layer breast prosthesis comprising a cured elastic material layer and an uncured self-shaping layer.

40. (New) A process for manufacturing a two-layer breast prosthesis comprising the steps of:

a) providing a breast mold comprising a lower component having a surface design configured to a desired breast shape and an upper component having a surface

design configured to a backside of the prosthesis;

b) placing a first film envelope and a second film envelope in the lower mold component, wherein the first film envelope and the second film envelope are joined along a common side edge, wherein said first film envelope and said second film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening;

c) at least partially filling the second film envelope of step a) by passing a curable elastic material precursor through the first fill opening and

d) at least partially filling the first film envelope of step a) by passing a non-crosslinking self-shaping dispersion through the second fill opening, wherein the non-crosslinking self-shaping dispersion comprises a plurality of microspheres dispersed in a silicone oil;

e) closing the upper and lower mold components about the at least partially filled first and second film envelopes; and

f) heating the closed mold to cure the elastic material precursor in the first film envelope and to provide a two-layer breast prosthesis comprising a cured elastic material layer and an uncured self-shaping dispersion layer.

41. (New) The process of claim 40, wherein the curable elastic material precursor of step b) comprises a silicone gel and a plurality of microspheres.

42. (New) The process of claim 40, wherein the first and second fill openings extend from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes.

43. (New) The process of Claim 40, wherein prior to step c) dissolved air is removed from the self-shaping dispersion.

44. (New) The process of Claim 37, wherein step c) comprises pumping the self shaping dispersion through the first fill opening in a closed configuration.